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K093630

JUN – 3 2010

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510(k) Summary

owner's name:	**Biodenta Swiss AG**
address:	**Tramstrasse 16** **9442 Berneck** **Switzerland**
phone:	+41 71 747 11 11
fax numbers:	+ 41 71 747 1112
name of contact person:	Mr. David Eiler
date the summary was prepared:	2009-11-30
name of the device:	**BIODENTA Dental Implant System**
trade or proprietary name:	**BIODENTA Dental Implant System**
the classification name:	implant, endosseous, root-form
	(21 CFR 872.3640 Product Code DZE)
Legally marketed device to which your firm is claiming equivalence:	The following predicate device is used to show the substantial equivalence concerning the general design the implant system
Company:	Straumann AG
Device:	Implant System Standard Plus
510(k) No.:	K081419

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Furthermore for the surface that is used for the BIODENTA Dental Implant System we consider the following product as predicate device:

Legally marketed device to which your firm is claiming equivalence	The following predicate device is used to show the substantial equivalence concerning the surface of the implant
Company	Nobel Biocare
Device	TIUNITE IMPLANTS
510(k) No.	K050705

Indications for Use

Biodenta dental implants intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.

Specific indications for small diameter (Ø 3.5 mm) implants: It is recommended not to place small implants with "NP" platform in the molar or premolar region.

Device Description:

The BIODENTA Dental Implant System is an integrated system of endosseous dental implants, which are designed to support prosthetic devices for partially or fully edentulous patients. The system consists of a variety of dental implants, abutments and surgical and prosthetic parts and instruments.

The technological characteristics of the BIODENTA Dental Implant System are equivalent to those of the predicate devices:

Element of comparison	**BIODENTA Dental Implant System** -new device-	Implant System Standard Plus **K081419** -predicate device-
System	Root form tissue level Implant	Root form tissue level Implant
Diameter / Platform (length) in mm	3.5 / 3.7 (8-14) 4.1 / 4.8 (8-14) 4.8 / 4.8 (8-14) 4.8 / 5.5 (8-12)	3.3 / 4.8 (8-14) 4.1 / 4.8 (6-14) 4.8 / 4.8 (6-14) 4.8 / 6.5 (6-12)
Material	Titanium Grade 4	Titanium Grade 4

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Element of comparison	BIODENTA Dental Implant System -new device-	Implant System Standard Plus K081419 -predicate device-
Abutment connection	Internal octagon	Internal octagon
Neck height	1.5 mm	1.8 mm
Surface Neck	Smooth	Smooth
Shoulder angle	45°	45°

The endosseous implants of the BIODENTA Dental Implant System are equipped with a Anodized Titanium oxide surface called: BST Surface .

The clinical data and the test results demonstrate that the BIODENTA Dental Implant System is as safe and effective as the legally marketed device Straumann AG, Implant System Standard Plus.

Summary of Nonclinical Testing:

Based on the risk analysis, performance testing was conducted to confirm compliance to device specifications; all functions were verified to operate as designed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 3 2010

David Eiler
Biodenta Swiss AG
Tramstrasse 16
Berneck
Switzerland 9442

Re: K093630
Trade/Device Name: Biodenta Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: May 12, 2010
Received: May 14, 2010

Dear Mr. Eiler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

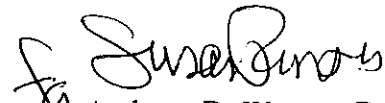
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): _____

Device Name:
BIODENTA Dental Implant System_____

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Specific indications for small diameter (Ø 3.5 mm) implants: It is recommended not to place small implants with "NP" platform in the molar or premolar region.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093630